K063378

5. 510 (K) SUMMARY

510(k) SUMMARY
(per 21 CFR §807.92)

JAN 26 2007

CIRRUS™ HD-OCT

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4481 (fax) Est. Reg. No. 2918630
Contact Person:	Judith A. Brimacombe, MA Director, Regulatory/Clinical Affairs Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4481 (fax)
Classification Name:	Ophthalmoscope
Classification:	Class II (acc. 21 CFR 886.1570)
Product Code:	86 HLI
Trade/Proprietary Name:	Cirrus™ HD-OCT

PREDICATE DEVICE

Company: Device:	Carl Zeiss Meditec, Inc. Stratus OCT™ with Retinal Nerve Fiber Layer Normative and Macula Database
Company: Device:	Carl Zeiss Meditec, Inc. Visante™ OCT

INTENDED USE

The Cirrus™ HD-OCT is intended for use in the viewing and axial cross sectional imaging of posterior ocular structures.

K063378

SECTION 5. 510(K) SUMMARY

INDICATIONS FOR USE

The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age- related macular degeneration and glaucoma.

DEVICE DESCRIPTION

The Cirrus™ HD-OCT is a computerized instrument that acquires and analyzes cross-sectional tomograms of posterior ocular structures (including retina, retinal nerve fiber layer, macula, and optic disc.). It employs non-invasive, non-contact, low-coherence interferometry to obtain these high-resolution images. Using this non-invasive optical technique, Cirrus HD-OCT produces high-resolution cross-sectional tomograms of the eye without contacting the eye.

SUBSTANTIAL EQUIVALENCE

The Cirrus™ HD-OCT is substantially equivalent to the predicate devices identified previously. The Cirrus™ HD-OCT is substantially equivalent to the predicate devices with regard to intended use, operating principle, function, and materials.

Evaluation performed on the Cirrus™ HD-OCT supports the indications for use statement and demonstrates the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness with respect to ophthalmoscopes.

CLINICAL EVALUATION

Clinical data was collected and evaluated to support the indications for use statement for the Cirrus™ HD-OCT and to demonstrate substantial equivalence to the Stratus OCT.

CONCLUSION

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Cirrus™ HD-OCT to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Carl Zeiss Meditec, Inc.
c/o Judy Brimacombe
Director, Regulatory/Clinical Affairs
5160 Hacienda Drive
Dublin, CA 94568

JAN 26 2007

Re: K063378
Trade/Device Name: Cirrus HD-OCT
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-Powered
Regulatory Class: Class II
Product Code: HLI
Dated: November 6, 2006
Received: November 8, 2006

Dear Ms. Brimacombe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Device Name: Cirrus™ HD-OCT

Indications for Use:

The Cirrus™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula, and optic disc. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age- related macular degeneration and glaucoma.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Butterfield

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K063378